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testosterone bound to one or more endogenous binders in said fluid comprising the steps of (a) forming a mixture of a sample of said fluid with (1) an amount of a specific antibody for the free testosterone insufficient to substantially affect said equilibrium, and (2) a labeled derivative of testosterone which is radioiodinated 6-hydroxy-testosterone-19-carboxymethyl ether histamine that binds to said antibody and has affinity for the endogenous binders lower than that of testosterone for said endogenous binders, (b) maintained said mixture to permit said labeled derivative to compete with the free testosterone for binding with the antibody, (c) measuring the amount of said labeled derivative that has, or has not, become bound to the antibody, and (d) determining the concentration of free testosterone from said measurement, wherein the improvement comprises including in the mixture an amount of a blocking agent which is sulfobromophthalein which substantially reduces the binding of said labeled derivative to the endogenous binders without substantially reducing the binding of testosterone to said endogenous binders.

REMARKS

Reconsideration is requested.

The new claim is specifically directed to the disclosure in the Specification, Example 1 on page 25 and 26. Note that this Example along with Example 2 on page 26-27 show that the radiolabeled analog and blocking agent recited in claim 54 is uniquely effective in preventing the disturbance of the equilibrium between free testosterone and testosterone

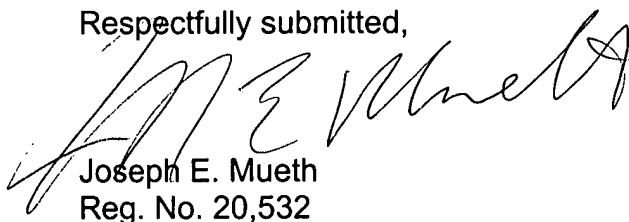
bound to endogenous binders such as albumin. Consequently, the use of these reagents is specifically effective in giving a true reading of the amount of free testosterone in a biological sample.

This combination of reagents is not disclosed or suggested in either Midgley et al United States Patent Number 4,366,143 or Midgley et al European Patent Number 155104 or Hertl et al British Patent Number 2085160A.

Further, this specific assay was not in any way involved in the Interference No. 101933.

The Notice of Allowance is requested.

Respectfully submitted,



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Date: June 1, 2000

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